

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER
ASSOCIATION, *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of Health and Human
Services, *et al.*,

Defendants.¹

Case No. 1:23-cv-00707-DAE

**DEFENDANTS' REPLY IN SUPPORT OF THEIR
CROSS-MOTION FOR SUMMARY JUDGMENT**

ERIC J. HAMILTON
Deputy Assistant Attorney General

JUSTIN R. SIMMONS
United States Attorney

MICHELLE R. BENNETT
Assistant Branch Director

STEPHEN M. PEZZI
Senior Trial Counsel
CASSANDRA M. SNYDER
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch

Counsel for Defendants

¹ Pursuant to Federal Rule of Civil Procedure 25(d), Robert F. Kennedy, Jr., Secretary of Health and Human Services, is automatically substituted as a defendant in his official capacity for his predecessor, Xavier Becerra. Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, is likewise automatically substituted as a defendant in his official capacity for his predecessor, Chiquita Brooks-Lasure.

TABLE OF CONTENTS

INTRODUCTION1

ARGUMENT1

I. PLAINTIFFS’ NONDELEGATION CLAIM IS MERITLESS.1

II. THE COURT LACKS JURISDICTION OVER PLAINTIFFS’ EXCISE-TAX CLAIM, WHICH IS ALSO MERITLESS.6

 A. Plaintiffs’ excise-tax claim is not redressable in this suit6

 B. Plaintiffs’ excise-tax claim is barred by the Anti-Injunction Act.....8

 C. Plaintiffs’ excise-tax claim is meritless.....12

III. PLAINTIFFS’ DUE PROCESS CLAIMS ARE MERITLESS 14

 A. Plaintiff PhRMA’s due process claim lacks merit..... 14

 B. Plaintiff NICA’s due process claim lacks merit 19

 C. Plaintiff GCCA’s due process claim lacks merit..... 20

CONCLUSION20

TABLE OF AUTHORITIES

Cases

<i>Acevedo v. Allsup's Convenience Stores, Inc.</i> , 600 F.3d 516 (5th Cir. 2010)	8
<i>Am. Power & Light Co. v. SEC</i> , 329 U.S. 90 (1946)	2, 6
<i>Associated Builders & Contractors, Inc. v. Foley</i> , 37 F.3d 945 (3d Cir. 1994)	16
<i>AstraZeneca Pharms. LP v. Becerra</i> , 719 F. Supp. 3d 377 (D. Del. 2024), <i>aff'd</i> , 137 F.4th 116 (3d Cir. 2025)	1
<i>AstraZeneca Pharms. LP v. HHS</i> , 137 F.4th 116, 125-26 (3d Cir. 2025)	1, 15, 16, 20
<i>Baker v. United States</i> , No. 79-2346, 1979 WL 1561 (E.D. La. 1979)	11
<i>Becerra v. Louisiana</i> , Nos. 21A240, 21A241, 2021 WL 8939385 (U.S. Dec. 30, 2021)	19
<i>Biden v. Missouri</i> , 595 U.S. 87 (2022)	17, 18
<i>Big Time Vapes, Inc. v. FDA</i> , 963 F.3d 436 (5th Cir. 2020)	1, 2, 3
<i>Biotechnology Indus. Org., v. v. District of Columbia</i> , 496 F.3d 1362 (Fed. Cir. 2007)	15
<i>Bob Jones Univ. v. Simon</i> , 416 U.S. 725 (1974)	9, 11, 12
<i>Boehringer Ingelheim Pharms., Inc. v. HHS</i> , No. 3:23-cv-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), <i>appeal filed</i> , No. 24-2092 (2d Cir Aug. 8, 2024)	<i>passim</i>
<i>Booker-El v. Superintendent</i> , 668 F.3d 896 (7th Cir. 2012)	16
<i>Bowles v. Willingham</i> , 321 U.S. 503 (1944)	17

<i>Bristol Myers Squibb Co. v. Becerra</i> , Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), <i>appeals filed</i> , Nos. 24-1820 & 24-1821 (3d Cir. May 6, 2024)	1, 18
<i>Cardinal Towing & Auto Repair, Inc. v. City of Bedford</i> , 180 F.3d 686 (5th Cir. 1999)	16
<i>Carter v. Carter Coal Co.</i> , 298 U.S. 238 (1936)	17
<i>Cent. Timber Dev., Inc. v. Wunnicke</i> , 467 U.S. 82 (1984)	16
<i>CIC Servs., LLC v. IRS</i> , 593 U.S. 209 (2021)	10
<i>Comm’r v. Shapiro</i> , 424 U.S. 614 (1976)	12
<i>Consumers’ Rsch. v. FCC</i> , 109 F.4th 743 (5th Cir. 2024)	5
<i>Davis v. Passman</i> , 442 U.S. 228 (1979)	19
<i>Dayton Area Chamber of Com. v. Becerra</i> , 696 F. Supp. 3d 440 (S.D. Ohio 2023)	1, 17
<i>Dep’t of Revenue of Montana v. Kurth Ranch</i> , 511 U.S. 767 (1994)	13
<i>Doe v. Univ. of Scis.</i> , 961 F.3d 203 (3d Cir. 2020)	19
<i>Douglass v. Nippon Yusen Kabushiki Kaisha</i> , 46 F.4th 226 (5th Cir. 2022)	18
<i>Enochs v. Williams Packing & Navigation Co., Inc.</i> , 370 U.S. 1 (1962)	8, 10, 11
<i>FCC v. Consumers’ Rsch.</i> , No. 24-354, 2025 WL 1773630 (U.S. June 27, 2025)	<i>passim</i>
<i>FDA v. Wages & White Lion Invs., LLC</i> , 145 S. Ct. 898 (2025)	3
<i>Fla. Bankers Ass’n v. Dep’t of the Treasury</i> , 799 F.3d 1065 (D.C. Cir. 2015)	12

<i>Flora v. United States</i> , 357 U.S. 63 (1960)	10
<i>Franklin v. United States</i> , 49 F.4th 429 (5th Cir. 2022)	8, 11
<i>Free Enter. Fund v. PCAOB</i> , 561 U.S. 477 (2010)	6
<i>Fuld v. PLO</i> , No. 24-151, 2025 WL 1716140 (U.S. June 20, 2025)	18
<i>Furlong v. Shalala</i> , 156 F.3d 384 (2d Cir. 1998)	19
<i>Garelick v. Sullivan</i> , 987 F.2d 913 (2d Cir. 1993)	18
<i>Gorney v. Veterans Admin.</i> , No. 18-cv-531, 2020 WL 5535757 (D. Ariz. Sept. 15, 2020)	20
<i>Gundy v. United States</i> , 588 U.S. 128 (2019)	2
<i>Haaland v. Brackeen</i> , 599 U.S. 255 (2023)	6
<i>Horne v. Dep’t of Agric.</i> , 576 U.S. 350 (2015)	17
<i>Hosp. Res. Pers., Inc. v. United States</i> , 68 F.3d 421 (11th Cir. 1995)	11
<i>Hosp. Res. Pers., Inc. v. United States</i> , 860 F. Supp. 1554 (S.D. Ga. 1994)	11
<i>J.W. Hampton, Jr., & Co. v. United States</i> , 276 U.S. 394 (1928)	2
<i>James v. Cleveland Sch. Dist.</i> , 45 F.4th 860 (5th Cir. 2022)	14
<i>Jarrett v. United States</i> , 79 F.4th 675 (6th Cir. 2023)	11
<i>Larson v. United States</i> , 888 F.3d 578 (2d Cir. 2018)	11

<i>Ledford v. Sullivan</i> , 105 F.3d 354 (7th Cir. 1997)	20
<i>Loving v. United States</i> , 517 U.S. 748 (1996)	5
<i>Mathews v. Eldridge</i> , 424 U.S. 319 (1976)	14
<i>Matter of Westmoreland Coal Co.</i> , 968 F.3d 526 (5th Cir. 2020)	8
<i>Muncaster v. Baptist</i> , 367 F. Supp. 1120 (N.D. Ala. 1973)	11
<i>Nat’l Broad. Co. v. United States</i> , 319 U.S. 190 (1943)	2
<i>Nat’l Fed’n of Indep. Bus. v. Sebelius</i> , 567 U.S. 519 (2012)	8, 18, 19
<i>Nat’l Infusion Ctr. Ass’n v. Becerra</i> , 116 F.4th 488 (5th Cir. 2024)	16, 20
<i>Nebbia v. New York</i> , 291 U.S. 502 (1934)	17
<i>Novartis Pharms. Corp. v. Becerra</i> , No. 23-14221, 2024 WL 4524357 (D.N.J. Oct. 18, 2024), <i>appeal filed</i> , No. 24-2968 (3d Cir. Oct. 21, 2024)	1, 9, 11, 12
<i>Novo Nordisk Inc. v. Becerra</i> , No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), <i>appeal filed</i> , No. 24-2510 (3d Cir. Aug. 19, 2024)	1, 2, 3, 6
<i>Nowik v. Comm’r</i> , No. 83-cv-0625, 1983 WL 1634 (E.D. Mich. 1983)	11
<i>Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.</i> , 299 U.S. 183 (1936)	17
<i>Olsen v. Nebraska</i> , 313 U.S. 236 (1941)	17
<i>Omar v. McHugh</i> , 646 F.3d 13 (D.C. Cir. 2011)	19, 20
<i>Pederson v. Unilever, N.V.</i> , No. SA-20-CV-20-XR, 2020 WL 8408970 (W.D. Tex. Apr. 17, 2020)	8

<i>Perkins v. Lukens Steel Co.</i> , 310 U.S. 113 (1940)	4, 5
<i>Riley v. Comm’r</i> , 566 F. Supp. 21 (S.D. Ohio 1983)	11
<i>Rock River Health Care, LLC v. Eagleson</i> , 14 F.4th 768 (7th Cir. 2021)	19
<i>Rocovich v. United States</i> , 933 F.2d 991 (Fed. Cir. 1991)	9
<i>RYO Mach. LLC v. Dep’t of Treasury</i> , 696 F.3d 467 (6th Cir. 2012)	10
<i>Solem v. Helm</i> , 463 U.S. 277 (1983)	14
<i>South Carolina v. Regan</i> , 465 U.S. 367 (1984)	8, 11
<i>Union Pacific R.R. Co. v. Public Serv. Comm’n of Mo.</i> , 248 U.S. 67 (1918)	17
<i>United States v. Bajakajian</i> , 524 U.S. 321 (1998)	12, 14
<i>United States v. Butler</i> , 297 U.S. 1 (1936)	17
<i>United States v. Clintwood Elkhorn Min. Co.</i> , 553 U.S. 1 (2008)	11
<i>United States v. Cooper</i> , 750 F.3d 263 (3d Cir. 2014)	1
<i>United States v. Grimaud</i> , 220 U.S. 506 (1911)	1
<i>United States v. Mackby</i> , 261 F.3d 821 (9th Cir. 2001)	13
<i>United States v. Salerno</i> , 481 U.S. 739 (1987)	3
<i>United States v. Schwarzbach</i> , 127 F.4th 259 (11th Cir. 2025)	12, 13

<i>United States v. Tingey</i> , 30 U.S. 115 (1831)	5
<i>United States v. Toth</i> , 33 F.4th 1 (1st Cir. 2022)	13
<i>United States v. Womack</i> , 654 F.2d 1034 (5th Cir. 1981)	4
<i>Webster v. Doe</i> , 486 U.S. 592 (1988)	12
<i>Whitman v. Am. Trucking Ass'ns</i> , 531 U.S. 457 (2001)	2

Statutes

26 U.S.C. § 5000D	7, 8, 9
26 U.S.C. § 6330(c)(2)(A)	9
26 U.S.C. § 7421(a)	8
26 U.S.C. § 7422	9
28 U.S.C. § 1346(a)(1)	9
28 U.S.C. § 1491	9
28 U.S.C. § 7482(a)(1)	9
31 U.S.C. § 3729(a)(1)	13
31 U.S.C. § 5321	13
42 U.S.C. § 1320f	2, 7
42 U.S.C. § 1320f-1	2, 7
42 U.S.C. § 1320f-2	2
42 U.S.C. § 1320f-3	2, 3, 4
42 U.S.C. § 1320f-5(a)(6)	7
42 U.S.C. § 1320f-7	5
42 U.S.C. § 1395w-3a	20
Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (2022)	5

Regulations

Excise Tax on Designated Drugs; Procedural Requirements,
89 Fed. Reg. 55,507 (July 5, 2024)7

Other Authorities

IRS Policy Statement 5-16, IRM 1.2.1.6.4(6)9

INTRODUCTION

Every court to consider the constitutionality of the Medicare Drug Price Negotiation Program has upheld it in full.² Plaintiffs in this case offer nothing new that would justify a departure from that nationwide consensus. On their nondelegation claim, Plaintiffs are swimming upstream against a century of adverse precedent—including the Supreme Court’s decision last week reversing the Fifth Circuit opinion on which several of Plaintiffs’ key nondelegation arguments depended. *See FCC v. Consumers’ Rsch.*, No. 24-354, 2025 WL 1773630 (U.S. June 27, 2025). On their excise-tax claim, Plaintiffs failed to sue the agency responsible for enforcing the tax, and in any event cannot evade the Anti-Injunction Act—and even if the Court had jurisdiction over that claim, Plaintiffs still haven’t identified any case, from any court, in which a tax was held to be a “fine” at all, let alone an “excessive” one, in violation of the Eighth Amendment. Finally, Plaintiffs’ due process claims fail because “[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs.” *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116, 125-26 (3d Cir. 2025).

ARGUMENT

I. Plaintiffs’ nondelegation claim is meritless.

Although Congress has delegated authority “from the beginning of the government,” *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (quoting *United States v. Grimaud*, 220 U.S. 506, 517 (1911)), “[o]n only two occasions has the Court invalidated legislation based on the nondelegation doctrine, and both occurred in 1935,” *United States v. Cooper*, 750 F.3d 263, 268 (3d Cir. 2014). There is nothing special about the IRA that warrants breaking that streak. Any doubt was resolved last week by the Supreme Court’s decision in *Consumers’ Research*, 2025 WL 1773630.

² *See AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024), *aff’d*, 137 F.4th 116 (3d Cir. 2025); *Dayton Area Chamber of Com. v. Becerra*, 696 F. Supp. 3d 440 (S.D. Ohio 2023); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal filed*, No. 24-2092 (2d Cir. Aug. 8, 2024); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *appeals filed*, Nos. 24-1820 & 24-1821 (3d Cir. May 6, 2024); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal filed*, No. 24-2510 (3d Cir. Aug. 19 2024); *Novartis Pharms. Corp. v. Becerra*, No. 23-14221, 2024 WL 4524357, at *2 (D.N.J. Oct. 18, 2024), *appeal filed*, No. 24-2968 (3d Cir. Oct. 21, 2024).

a. Defendants will start (again) with what Plaintiffs, tellingly, still refuse to address: the operative legal standard. Per a century of binding precedent, if a statute sets forth an “intelligible principle” to guide the agency, it effects a lawful grant of discretion to the Executive Branch. *Id.* at *8 (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)). Congress satisfies the “intelligible principle” test if it defines “the general policy” for the agency to pursue and “the boundaries of [the] delegated authority.” *Id.* (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)). That test is “not demanding.” *Gundy v. United States*, 588 U.S. 128, 146 (2019) (plurality op.).

Given these principles, Defendants’ opening brief noted that “the phrase ‘intelligible principle’ does not appear once in Plaintiffs’ brief.” Defs.’ Br. at 9, ECF No. 70. Remarkably, the same is true of their opposition—other than one dismissive quotation to the *government’s* brief. *See* Pls.’ Opp’n & Reply at 7, ECF No. 85 (“Despite the government’s emphasis on ‘intelligible principles,’ . . .”). Nowhere do Plaintiffs engage with that operative legal standard, much less refute Defendants’ explanation of why it is satisfied. That alone is fatal to their claim, as “the intelligible-principle standard has focused our nondelegation doctrine for a century.” *Consumers’ Rsch.*, 2025 WL 1773630, at *8.

Plaintiffs’ reluctance to grapple with the “intelligible principle” standard is, in a sense, understandable—as the IRA provides far more guidance than many statutes that have satisfied it. If Congress can direct the EPA to “protect the public health,” *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 472 (2001), or the FCC to regulate in the “public interest, convenience, or necessity,” *Nat’l Broad. Co. v. United States*, 319 U.S. 190, 225-26 (1943), it is impossible to say that this statute goes too far.

Defendants will not block quote (again) all of the IRA’s detailed statutory criteria, *see* Defs.’ Br. at 12-13 (quoting 42 U.S.C. § 1320f-3(e)(1), (e)(2)), nor dwell on the many other ways in which “Congress restricted the Secretary’s discretion by making many of the key regulatory decisions itself,” *Big Time Vapes*, 963 F.3d at 445; *see* Defs.’ Br. at 11-12 (citing 42 U.S.C. § 1320f(b), (c) (defining terms); *id.* § 1320f-1 (criteria for negotiation-eligible and selected drugs); *id.* § 1320f-3(c) (formulae for ceiling prices); *id.* § 1320f-3 (negotiation procedures and timing); *id.* § 1320f-2 (parameters for agreements with manufacturers)). In short, the IRA “provides significantly much more guidance than Plaintiffs claim,” *Novo Nordisk*, 2024 WL 3594413, at *8, and it “falls comfortably within the outer boundaries

demarcated by the Supreme Court,” *Big Time Vapes*, 963 F.3d at 444.

b. It is not clear that Plaintiffs even dispute that this statute is far more specific than those upheld in prior delegations. Instead, Plaintiffs assert that “the ‘factors’ that the IRA outlines for HHS to ‘consider’ impose no meaningful constraint on the agency,” because (in Plaintiffs’ view) “CMS can give each factor as much or as little weight as it chooses,” Pls.’ Opp’n & Reply at 9, or perhaps can even “*ignore* all of the statutory ‘criteria’” entirely, *id.* at 4. Plaintiffs are mistaken.

Congress provided that CMS “shall consider” several factors in “determining the offers and counteroffers” during price negotiations. 42 U.S.C. § 1320f-3(e). So when Plaintiffs say that “the IRA permits HHS to simply *ignore* all of the statutory ‘criteria,’” Pls.’ Opp’n & Reply at 4, they are wrong. If CMS “ignore[d] all of the statutory criteria” that Congress said it “shall consider,” CMS would be violating the law—whether or not that hypothetical violation is subject to judicial review.

Moreover, Plaintiffs have always characterized this suit as a challenge to “the facial constitutionality of a federal statute.” Jt. Scheduling Mot. ¶ 5, ECF No. 33. “A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid.” *United States v. Salerno*, 481 U.S. 739, 745 (1987). Plaintiffs cannot meet that high bar with baseless speculation that the agency might ignore Congress’s directives. To the contrary, “agencies are entitled to a presumption of regularity.” *FDA v. Wages & White Lion Invs., LLC*, 145 S. Ct. 898, 922 (2025).

As for the softer version of Plaintiffs’ argument—that “CMS can give each factor as much or as little weight as it chooses,” Pls.’ Opp’n & Reply at 9—there is nothing unusual (let alone unconstitutional) about an agency having discretion to weigh various criteria in carrying out delegated authority. Indeed, the Supreme Court rejected a nondelegation challenge to a similar statute just last week. *See Consumers’ Rsch.*, 2025 WL 1773630, at *5-6 (“the FCC ‘shall consider the extent to which’ a service” meets several general “criteria” and “principles”). Plaintiffs’ arguments to the contrary “would throw a host of federal statutes into doubt,” *id.* at *9, and find support only in Justice Gorsuch’s dissent, *see id.* at *32 (Gorsuch, J., dissenting) (lamenting that that statute “instructs the FCC” to consider “the primordial soup of four factors found in § 254(c)(1), as supplemented by six

principles discussed in §§ 254(b)(1)-(6),” even though “[m]any of these factors and principles address[] competing goods,” making it hard to “weigh them”). That position did not carry the day.

Even beyond the factors that CMS “shall consider” in 42 U.S.C. § 1320f-3(e), Plaintiffs face another problem: Congress provided very rigid (and very specific) mathematical formulae that set the “ceiling price” for CMS’s offers. For some drugs, that price will be either 75 percent (“short-monopoly drugs”), 65 percent (“extended-monopoly drugs”), or 40 percent (“long-monopoly drugs”) of “the average non-Federal average manufacturer price for such drug for 2021,” adjusted for inflation, *id.* § 1320f-3(c)(1)(C)(ii)(I), (c)(3)—commonly known in the industry as the “non-FAMP price.” Other drugs are subject to different (but also complex) formulae. *See, e.g., id.* § 1320f-3(c)(1)(B)(i), (c)(2) (referencing the “price of the drug under . . . part D of subchapter XVIII, net of all price concessions,” known as the “Part D net price”); *see also id.* § 1320f-3(c)(1)(B)(ii), (c)(1)(C)(i), (c)(3), (c)(1)(C)(ii)(I). Those upper bounds could hardly be *more* specific. For the lower bound, CMS has more flexible but equally straightforward orders: to “aim[] to achieve the lowest maximum fair price for each selected drug” that it can negotiate, accounting for the statutory factors. *Id.* § 1320f-3(b)(1). The nondelegation analysis is “trained on intelligible principles, not on numeric caps” or “mathematical formula[s],” *Consumers’ Rsch.*, 2025 WL 1773630, at *9—but in this statute, Congress provided all of the above.

As for the ceiling price formulae, Plaintiffs’ only response is that these constraints “offer[] no protection to Plaintiffs, who are concerned about prices being too *low*,” not too high. Pls.’ Opp’n & Reply at 9. But the nondelegation doctrine is not “concerned about prices being too low” *or* too high, *id.*—only with ensuring that the agency is constrained by some intelligible principle. And here, it is.

c. Plaintiffs still ignore that, in reviewing a nondelegation claim, “[t]he standards of the statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute and its factual background and the statutory context in which the standards appear.” *United States v. Womack*, 654 F.2d 1034, 1037 (5th Cir. 1981); *accord Consumers’ Rsch.*, 2025 WL 1773630, at *13 (same). Here, that “statutory context” strongly favors the government, because this is a “delegation governing the negotiation of individual contracts,” which Plaintiffs do not dispute is “a traditional Executive Branch function.” Defs.’ Br. at 13; *see Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940).

In the context of a delegation in an area of traditional executive authority, “the question to be asked is not whether there was any explicit principle telling the” agency how to exercise its statutory discretion, “but whether any such guidance was needed, given the nature of the delegation and the officer who is to exercise the delegated authority.” *Loving v. United States*, 517 U.S. 748, 772 (1996). In other words, in the context of what is typically an “unrestricted power” of the Executive Branch, the level of specificity required to satisfy the nondelegation doctrine is lower. *Perkins*, 310 U.S. at 127; *cf. United States v. Tingey*, 30 U.S. 115, 126 (1831) (“There is no statute of the United States expressly defining the duties of pursers in the navy.”). Defendants pressed these points in their opening brief. *See* Defs.’ Br. at 13 (citing *Perkins*, 310 U.S. at 127). Plaintiffs offered no response.

d. Unable to satisfy the intelligible-principle test, Plaintiffs’ nondelegation arguments now rest largely on the purported absence of “administrative and judicial oversight,” due to the IRA’s (partial) preclusion provision, 42 U.S.C. § 1320f-7, as well as the waiver of notice-and-comment requirements for the first three negotiation cycles, Pub. L. No. 117-169, § 11001(c). But Defendants already explained, and Plaintiffs do not dispute, that preclusion of review is both routine and lawful, especially in Medicare. *See* Defs.’ Br. at 14-16. Defendants also explained, and Plaintiffs do not dispute, *see id.* at 16-17, that notice and comment, especially in Medicare, is a relatively recent procedural innovation; Plaintiffs still cite no case holding that it is constitutionally required (or even constitutionally relevant).

Plaintiffs clarify that they “are not arguing that the preclusion of review *alone* renders the IRA unconstitutional,” but instead assert that “[t]he statute’s nondelegation problem is its sweeping grant of vast discretion *combined with*” the streamlined administrative process and preclusion. Pls.’ Opp’n & Reply at 8; *see also id.* (quoting *Consumers’ Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024) (en banc) (“[T]wo or more things that are not independently unconstitutional *can combine* to violate the Constitution’s separation of powers.”)). But even accepting the (incorrect) premise that this statute contains some unusually “sweeping grant of vast discretion” to the agency, *id.*; *but see supra* at 2-4, Plaintiffs’ “combination” theory did not survive the Supreme Court’s decision in *Consumers’ Research*.

The Fifth Circuit “founded its combination theory—that a constitutional non-violation plus a constitutional non-violation may equal a constitutional violation—on [the Supreme Court’s] decision

in *Free Enterprise Fund*,” which “struck down a statute because it gave an executive officer two ‘layers of protection’ from the President’s removal authority.” *Consumers’ Rsch.*, 2025 WL 1773630, at *18 (quoting *Free Enter. Fund v. PCAOB*, 561 U.S. 477, 483 (2010)). But the “analogy and associated logic do not work.” *Id.* In *Free Enterprise Fund*, “the two layers of restrictions operated on a single axis with the one exacerbating . . . the other.” *Id.* That was not the case in *Consumers’ Research*, and that is not the case here: Plaintiffs’ varied complaints about (1) the flexibility of the statutory criteria, (2) limits on judicial review, and (3) the temporary waiver of notice-and-comment “do not operate on the same axis (save if it is defined impossibly broadly).” *Id.*; see also *Novo Nordisk*, 2024 WL 3594413, at *8 (“[P]reclusion of judicial review is not related to the nondelegation doctrine.”). And “[t]wo wrong claims do not make one that is right.” *Consumers’ Rsch.*, 2025 WL 1773630, at *18.³

II. The Court lacks jurisdiction over Plaintiffs’ excise-tax claim, which is also meritless.

Plaintiffs’ excise-tax claim faces two jurisdictional bars: (1) the redressability requirement of Article III standing; and (2) the Anti-Injunction Act. Plaintiffs’ arguments to the contrary lack merit.

A. Plaintiffs’ excise-tax claim is not redressable in this suit.

As explained in *Haaland v. Brackeen*, 599 U.S. 255, 291-96 (2023) (cited in Defs.’ Br. at 19-20), a plaintiff lacks standing if it fails to sue the entities responsible for its injuries. The Department of the Treasury and the IRS are the only entities responsible for enforcing the excise tax, but Plaintiffs have sued neither. In response, Plaintiffs do not dispute Defendants’ reading of *Haaland v. Brackeen*. Instead, they try to persuade this Court that they know better than the federal government does about the division of labor among different government agencies, asserting that “HHS fills an integral role”

³ *Consumers’ Research* does make one brief, passing reference to judicial review. See 2025 WL 1773630, at *8 (“[W]e have asked if Congress has provided sufficient standards to enable both ‘the courts and the public [to] ascertain whether the agency’ has followed the law.”). But, as in many of the opinions Plaintiffs’ cite, see Pls.’ Opp’n & Reply at 5-7, that reference is still about the specificity of the delegation required to satisfy the intelligible-principle test—it is not a suggestion that the presence or absence of judicial review, writ large, is itself a separate part of the nondelegation inquiry. To the contrary, *Consumers’ Research* explicitly and repeatedly reaffirms “the usual intelligible-principle test.” 2025 WL 1773630, at *12 (citing *Am. Power & Light*, 329 U.S. at 105).

in enforcing the excise tax. Pls.’ Opp’n & Reply at 18. But Plaintiffs overstate HHS’s role.

Tax liability accrues for manufacturers of designated drugs that choose not to sign a negotiation agreement or to agree to a maximum fair price—without any action by HHS. 26 U.S.C. § 5000D. For example, for initial price applicability year 2028, the tax is imposed beginning on March 1, 2026, and “ending on the earlier of” “the first date on which the manufacturer of such designated drug has in place [a negotiation agreement]” or “the date that the [HHS Secretary]” determines the standards for deselection found in 42 U.S.C. § 1320f-1(c) have been satisfied. 26 U.S.C. § 5000D(b)(1) (emphasis added); *see also* 42 U.S.C. § 1320f-1(c) (describing deselection standards). The tax is also imposed beginning on November 2, 2026, and “ending on the earlier of” “the first date on which the manufacturer of such designated drug and the [HHS Secretary] have agreed to a maximum fair price” or “the date that the” Secretary determines the standards for deselection have been satisfied. 26 U.S.C. § 5000D(b)(2) (emphasis added). For each of these periods, *see id.* § 5000D(b)(1), (2), HHS may play a role, but that role is to make determinations that could stop—not start—accrual of tax liability.

In response, Plaintiffs rely entirely on 42 U.S.C. § 1320f-5(a)(6). But that provision does not make HHS responsible (or even necessary) for assessing or enforcing the excise tax. Instead, HHS is empowered to “carry out” various “administrative duties,” including sharing “such information as is necessary to determine the tax imposed by [§] 5000D.” 42 U.S.C. §§ 1320f(a)(4), 1320f-5(a)(6). “[S]uch information” includes “the date on which the Secretary receives notification of any termination of an agreement” to participate in Medicare. *Id.* § 1320f-5(a)(6)(A)–(C). Again, in other words, HHS is authorized to provide Treasury with information that could *terminate* tax liability; that information is not necessary to “enforc[e] the excise tax provisions.” Pls.’ Opp’n & Reply at 17.

Were there any doubt, last year, the IRS published a final rule regarding a taxpayer’s obligations to self-report its excise-tax liability—without any involvement from HHS or CMS. IRS, *Excise Tax on Designated Drugs; Procedural Requirements*, 89 Fed. Reg. 55,507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47). In other words, a manufacturer would be responsible for self-reporting and paying any tax liability—regardless of whether HHS or CMS shares any information with the IRS. Under this regime, an injunction against HHS or CMS, standing alone, gets Plaintiffs nothing.

Plaintiffs suggest that “the Court can alleviate any issue simply by adding the necessary parties under Federal Rule of Civil Procedure 21.” Pls.’ Opp’n & Reply at 18. But Plaintiffs have never actually moved for leave to amend their complaint or to add new parties. Presumably, that is for the same reason that they omitted Treasury and IRS from the caption in the first place: because doing so would shine an even brighter spotlight on their separate problem with the Anti-Injunction Act. *See infra* at 8-12. Seeking an injunction against the IRS would have made it even more obvious that this claim is a prohibited effort to “restrain[] the assessment or collection of any tax.” 26 U.S.C. § 7421(a). In any case, especially without any motion requesting relief, this Court need not (and should not) exercise its discretion to rescue the leading trade association for pharmaceutical companies, nor its sophisticated counsel, from the consequences of their own litigation tactics. *See, e.g., Acevedo v. Allsup’s Convenience Stores, Inc.*, 600 F.3d 516, 521 (5th Cir. 2010) (“[D]istrict courts have the discretion to refuse joinder in the interest of avoiding prejudice and delay, ensuring judicial economy, or safeguarding principles of fundamental fairness.”); *Pederson v. Unilever, N.V.*, 2020 WL 8408970, at *1 (W.D. Tex. Apr. 17, 2020) (district court “may consider factors such as undue delay, bad faith or dilatory motive”).

B. Plaintiffs’ excise-tax claim is barred by the Anti-Injunction Act.

“[A]bsent limited exceptions, ‘no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person.’” *Franklin v. United States*, 49 F.4th 429, 434 (5th Cir. 2022) (quoting 26 U.S.C. § 7421(a)). So these taxpayers must do what taxpayers routinely do to challenge a tax: first pay the tax, then bring a refund suit.

Plaintiffs appear not to contest that the plain text of the AIA, on its face, applies to this claim. That is unsurprising, because (1) Congress labeled the excise tax a “tax” and (2) the purpose of this claim is to “restrain[] the assessment or collection” of that tax. 26 U.S.C. § 7421(a); *see also id.* § 5000D (calling it a “tax”). And “[w]ith the AIA, form—specifically, the label Congress uses—does matter over substance.” *Matter of Westmoreland Coal Co.*, 968 F.3d 526, 534 (5th Cir. 2020); *accord Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544, 564 (2012). So this claim could only survive via one of the two narrow, judge-made exceptions to the AIA: either (1) *Enochs v. Williams Packing & Navigation Co., Inc.*, 370 U.S. 1 (1962), or (2) *South Carolina v. Regan*, 465 U.S. 367 (1984). Neither applies here.

1. As for *Williams Packing*, Plaintiffs do not dispute that this “stringent” exception requires “proof of the presence of two factors”: “first, irreparable injury,” and “second, certainty of success on the merits.” *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974). As both courts to consider this precise question have held, Plaintiffs “cannot meet either of these requirements.” *Boehringer Ingelheim*, 2024 WL 3292657, at *22; *accord Novartis*, 2024 WL 4524357, at *4-5 (same).

Plaintiffs do not dispute that they could file a refund suit in federal district court or in the Court of Federal Claims after the tax is imposed on just a single sale of a single drug. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491. Nor that, if the IRS takes any collection action in connection with unpaid excise tax, the manufacturer could raise a constitutional challenge during a collection due process (“CDP”) hearing and, if unsuccessful, seek review in the Tax Court, *see* 26 U.S.C. § 6330(d)(1), then in the Court of Appeals, *see id.* § 7482(a)(1).

Plaintiffs likewise do not dispute that this is a “divisible” tax, meaning that it is imposed on each “sale” of a designated drug, *id.* § 5000D(a), which means that a taxpayer need only pay “the excise tax on a single transaction” before bringing a refund suit, *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). And “[w]hen a refund suit is pending on a divisible assessment, the [IRS] will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy.” IRS Policy Statement 5-16, IRM 1.2.1.6.4(6); *accord Boehringer Ingelheim*, 2024 WL 3292657, at *22 (“Due to the IRS’s forbearance policy, the harm during this interim period is minimal.”); *Novartis*, 2024 WL 4524357, at *4-5 (same).

Without any basis, however, Plaintiffs speculate that the IRS might ignore its own policy statement. *See* Pls.’ Opp’n & Reply at 20. That fear is unfounded and, in any event, if the IRS did seek to collect the excise tax during a refund suit, the taxpayer could challenge the propriety of that effort in light of the policy statement. *See* 26 U.S.C. § 6330(c)(2)(A) (a taxpayer “may raise at the [CDP] hearing any relevant issue relating to the unpaid tax or the proposed levy”).

Ultimately, Plaintiffs argue that even if the tax is divisible, and even if they could thus bring a refund suit after paying the tax on just a single sale, and even if the IRS would not seek to collect any further tax during that refund suit, they still need preemptive relief now because they would not know

for sure whether other future sales would eventually generate a large tax bill. *See* Pls.’ Opp’n & Reply at 20-21. But this argument does not show that the government “misunderstands . . . the nature of liability,” *id.* at 20, as Plaintiffs say—it shows that Plaintiffs misunderstand the Anti-Injunction Act.

Plaintiffs’ position essentially boils down to a policy disagreement with Congress: in Plaintiffs’ eyes, large corporate taxpayers that are engaged in sizeable or frequent transactions that may trigger substantial tax liability should not have to wait to challenge the constitutionality of a tax until after paying it. *See id.* at 20-21. But Congress chose a different path “when the dispute is about a tax,” as it is here: a taxpayer’s “sole recourse is to pay the tax and seek a refund.” *CIC Sems., LLC v. IRS*, 593 U.S. 209, 225 (2021); *see also, e.g., Flora v. United States*, 357 U.S. 63, 75-76 (1960) (“[T]he requirement of full payment may in some instances work a hardship,” but that is “a matter for Congress, not this Court.”). Put differently, this argument is just another way of Plaintiffs saying they would prefer to challenge the tax before paying it—exactly what the AIA has long forbidden. *RYO Mach. LLC v. Dep’t of Treasury*, 696 F.3d 467, 471 (6th Cir. 2012) (“The AIA has been interpreted broadly to encompass almost all premature interference with the assessment or collection of any federal tax.”).

To be clear, Plaintiffs’ members are not at all unique in this regard; corporate taxpayers often must engage in large transactions without fully knowing the tax consequences, setting aside reserves to pay any amount of tax that is ultimately due. If anything, Plaintiffs’ members are better positioned than most, because this tax is divisible, such that they will not have to pay tax on more than a single transaction before they can press their constitutional claim. At that point, if Plaintiffs prevail—which they (wrongly) believe is a certainty, *see* Pls.’ Opp’n & Reply at 21—then “the IRS could not require it to pay the tax at all and would have to refund any amount [the manufacturer] had already paid.” *Boehringer Ingelheim*, 2024 WL 3292657, at *22. On the other hand, if the manufacturer “did not prevail, the IRS could constitutionally require it to pay the tax, which would mean the tax inflicted no actionable harm” in the interim. *Id.* Either way, the first requirement of *Williams Packing* is unsatisfied.

Even if these options for judicial review were inadequate, *Williams Packing* would still not apply here because Plaintiffs cannot show that, on the second requirement, “under the most liberal view of the law and the facts,” “it is clear that under no circumstances could the Government ultimately

prevail” on the merits. 370 U.S. at 7. For the reasons below, *see infra* Section II.C, Plaintiffs have not come close to establishing a “certainty of success on the merits,” *Bob Jones*, 416 U.S. at 737 (emphasis added)—a very high bar, especially where Plaintiffs have still failed to identify any case holding that a tax is either a “fine” or an “excessive” one under the Eighth Amendment.⁴

2. The *South Carolina v. Regan* exception likewise does not apply because “a refund suit is an adequate remedy.” *Novartis*, 2024 WL 4524357, at *4. And *South Carolina v. Regan* “holds only that [the AIA] does not apply when Congress has failed to provide ‘an alternative remedy.’” *Jarrett v. United States*, 79 F.4th 675, 684 (6th Cir. 2023) (quoting 465 U.S. 367, 381 (1984)). Here, Plaintiffs have “an adequate remedy; [they] simply [don’t] like it.” *Larson v. United States*, 888 F.3d 578, 589 (2d Cir. 2018) (requiring plaintiff to pay \$61 million tax, then seek a refund, before pressing Excessive Fines claim).

3. Finally, Plaintiffs resort to the argument that, maybe, the Anti-Injunction Act is *itself* unconstitutional (or at least as applied here). *See* Pls.’ Opp’n & Reply at 19, 22. That is a bold argument—the statute was enacted in 1867, Plaintiffs cite no case reaching that conclusion, and Defendants are aware of none.⁵ The AIA has been applied for more than 150 years—often to constitutional claims—without any hint of a constitutional problem. *See, e.g., United States v. Clintwood Elkhorn Min. Co.*, 553 U.S. 1, 10 (2008) (“[T]he taxpayer must succumb to an unconstitutional tax, and seek recourse only after it has been unlawfully exacted”). That includes *Williams Packing* itself, despite concerns about the “ruination of the taxpayer’s enterprise” that would result from enforcing the statute as written. 370 U.S. at 6.

⁴ The only *Williams Packing* case that Plaintiffs cite is *Hospital Resource Personnel, Inc. v. United States*, 860 F. Supp. 1554, 1556 (S.D. Ga. 1994), which granted a TRO enjoining the IRS’s efforts to collect certain taxes. But although Plaintiffs don’t mention it, the Eleventh Circuit unanimously reversed the injunction in that case: holding that, even though the challenger was *correct* on the merits, the district court lacked jurisdiction under the AIA. *Hosp. Res. Pers., Inc. v. United States*, 68 F.3d 421, 428-29 (11th Cir. 1995). It explained that, under *Williams Packing*, “a court may not grant such an injunction merely because collection of a tax would cause irreparable harm to the taxpayer’s enterprise.” *Id.* at 428. And there, *Williams Packing* did not apply because, *ex ante*, “the government had at least the legal possibility of prevailing.” *Id.* at 429. So too here. Regardless, it is telling that Plaintiffs’ best case is a 31-year-old TRO opinion that was unanimously rejected on appeal.

⁵ Several courts have rejected similar arguments. *See Riley v. Comm’r*, 566 F. Supp. 21, 24 (S.D. Ohio 1983); *Nowik v. Comm’r*, 1983 WL 1634 (E.D. Mich. 1983); *Baker v. United States*, 1979 WL 1561 (E.D. La. 1979); *Muncaster v. Baptist*, 367 F. Supp. 1120, 1123 (N.D. Ala. 1973).

In any event, even taken on its own terms, the argument fails. Because a refund suit is available here, the only “issue here is when—not if—[Plaintiffs’ members] may challenge” the excise tax. *Fla. Bankers Ass’n v. Dep’t of the Treasury*, 799 F.3d 1065, 1067 (D.C. Cir. 2015) (Kavanaugh, J.). So “[t]his is not a case in which an aggrieved party has no access at all to judicial review.” *Bob Jones*, 416 U.S. at 746. It may be right that “deny[ing] any judicial forum for a colorable constitutional claim” would raise “serious constitutional question[s],” *Webster v. Doe*, 486 U.S. 592, 603 (1988)—those questions just don’t arise here. Likewise, because nobody contests the existence of the *Williams Packing* and *South Carolina v. Regan* exceptions, it doesn’t matter here whether they are constitutionally required.⁶ Because “the standard required by the [AIA] is at least as favorable to the taxpayer as that required by the Constitution,” the result would “not be affected by the resolution of the constitutional issue.” *Comm’r v. Shapiro*, 424 U.S. 614, 633 (1976). So Plaintiffs’ inability to satisfy the AIA—and the availability of a refund suit—is also fatal to any (belated, unpleaded) constitutional challenge to the AIA itself.⁷

C. Plaintiffs’ excise-tax claim is meritless.

Even if the Court had jurisdiction, the excise tax does not run afoul of the Excessive Fines Clause of the Eighth Amendment because it is neither a “fine,” nor an “excessive” one.

1. The excise tax is not a “fine” covered by the Eighth Amendment because it is not “punishment for some offense.” *United States v. Bajakajian*, 524 U.S. 321, 327 (1998). It is still the case that Plaintiffs have “not identified a case that has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes.” *Novartis*, 2024 WL 4524357, at *5; accord *Boehringer Ingelheim*, 2024 WL 3292657, at *23. Plaintiffs do now respond with two out-of-circuit cases. See Pls.’ Opp’n & Reply at 12, 21. But neither involves taxes at all, and in both, the legislature explicitly referred to the sanctions at issue as “penalties.” See *United States v. Schwarzbach*, 127 F.4th 259, 265 (11th Cir. 2025) (discussing the “maximum civil penalty for a willful violation of

⁶ To that end, a tax “requiring anyone who criticizes the government to pay \$100 billion,” or “a \$1 trillion tax on church attendance” would surely satisfy *Williams Packing*. Pls.’ Opp’n & Reply at 19. Those hyperbolic hypotheticals thus undermine, rather than support, Plaintiffs’ position.

⁷ Plaintiffs do not dispute “that the federal tax exception to the Declaratory Judgment Act is at least as broad as the Anti-Injunction Act.” *Bob Jones*, 416 U.S. at 732 n.7; see Pls.’ Opp’n & Reply at 22 n.13; Defs.’ Br. at 24. So, because the AIA applies, declaratory relief is also unavailable.

the FBAR reporting requirements”) (citing 31 U.S.C. § 5321(a)(5)(C)(i), (D)(ii)); *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001) (analyzing False Claims Act liability provision, 31 U.S.C. § 3729(a)(1), which states any person who knowingly presents a false claim “is liable to the [government] for a civil penalty” and treble damages). Moreover, both of those civil “penalties” also apply to conduct that was not only culpable, but punishable as a crime. *See Schwarzbau*m, 127 F.4th at 282 (“Congress also authorized a criminal penalty of five years’ imprisonment for each of the three years Schwarzbaum failed to file.”); *Mackby*, 261 F.3d at 827 (discussing legal standard for “a criminal FCA proceeding”).⁸ So those cases not only fail to refute Defendants’ central point—that Plaintiffs seek the first ever opinion holding that a tax is an excessive fine—they are fully consistent with Defendants’ theory.

The fact that this tax applies to otherwise “innocent conduct” is far from “absurd.” Pls.’ Opp’n & Reply at 14. To the contrary, “innocuous conduct like working or shopping” is often subject to taxation, *id.*, without the need for any analysis under the Eighth Amendment. Plaintiffs respond that “[u]nwarranted punishment is still punishment.” *Id.* But what Plaintiffs are still missing is that a tax on “working or shopping” is not “[u]nwarranted punishment,” it is a tax—not punishment at all. So too here. Plaintiffs’ hypothetical about “a prison term” for “working or shopping” is even further afield—incarceration is (obviously) “punishment” that *is* subject to Eighth Amendment scrutiny.

Otherwise, Plaintiffs fail to respond to most of Defendants’ arguments as to why this tax is not a “fine” at all. Plaintiffs do not dispute that *Department of Revenue of Montana v. Kurth Ranch*, 511 U.S. 767 (1994), rested on features—a state drug tax imposed on criminal activity—that are absent here. Similarly, Plaintiffs offer no real response to the point that *Kurth Ranch* squarely rejected the deterrent-in-part test on which Plaintiffs continue to so heavily rely—a test that has never been applied by the Supreme Court in the tax context. *See* Defs.’ Br. at 26-29. Finally, Plaintiffs mostly ignore Defendants’ arguments distinguishing *Austin* and *Bajakajian*—the only cases Plaintiffs cited in their opening brief in which a court held that an exaction constituted a “fine” for purposes of the Excessive

⁸ Although inapposite here, *Schwarzbau*m is also contradicted by *United States v. Toth*, 33 F.4th 1, 19 (1st Cir. 2022) (“[W]e conclude that a civil penalty imposed under § 5321(a)(5)(C)-(D) is not a ‘fine’ and as such the Excessive Fines Clause of the Eighth Amendment does not apply to it.”).

Fines Clause. As explained, the exactions in those cases—the *in rem* civil forfeiture in *Austin* and the criminal forfeiture in *Bajakajian*—bear no resemblance to this excise tax. *See* Defs.’ Br. at 25-26.

2. Even if Plaintiffs could establish that the excise tax is a “fine” for Excessive Fines Clause purposes, it is not an “excessive” one. Plaintiffs continue to criticize IRS’s interpretation of the scope and reach of the excise tax, calling IRS’s interpretation an effort to “rewrite the law to make it less disproportionate,” Pls.’ Opp’n & Reply at 15—an argument that Defendants have already addressed, and that Plaintiffs lack standing to press (especially on a facial challenge). *See* Defs.’ Br. at 28 n.16. Plaintiffs also argue that “[n]o punishment is proportional to ‘the gravity’ of entirely innocent conduct.” Pls.’ Opp’n & Reply at 14. Again, Defendants have explained why the nature of the conduct at issue reinforces why the Court should not reach the excessiveness inquiry in the first place. *See supra* at 13, Defs.’ Br. at 30. But it is telling that, on Plaintiffs’ view, it seems that *every* sales or income tax would be disproportionate, in violation of the Eighth Amendment. That can’t be right.

Finally, Plaintiffs fail to meaningfully engage with Defendants’ analysis of the proportionality test—other than by criticizing binding precedent. *See* Pls.’ Opp’n & Reply at 15 n.8 (disparaging a Fifth Circuit decision cited by the government as “completely circular”). For example, Plaintiffs do not dispute that a court must afford “substantial deference” to Congress in this context. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *see also Bajakajian*, 524 U.S. at 336. And Plaintiffs hardly even attempt to refute Defendants’ analysis of the *Bajakajian* factors. *See* Defs.’ Br. at 30-31.

III. Plaintiffs’ due process claims are meritless.

Plaintiffs fail to establish the first requirement of a due process claim because the IRA does not deprive manufacturers, providers, or patients of any protected property interest.⁹

A. Plaintiff PhRMA’s due process claim lacks merit.

At its core, both of Plaintiffs’ alleged manufacturer property interests boil down to a right to

⁹ Plaintiffs suggest that Defendants have “concede[d]” each of the individual factors under the second prong of the procedural due process analysis in *Mathews v. Eldridge*, 424 U.S. 319 (1976). *See* Pls.’ Opp’n & Reply at 22. To the contrary, as Defendants explained, “[t]here is . . . no need for the Court to address” that analysis where, as here, there is no “‘cognizable interest in liberty or property.’” Defs.’ Br. at 32 (quoting *James v. Cleveland Sch. Dist.*, 45 F.4th 860, 864 (5th Cir. 2022)).

demand that the government pay drug manufacturers’ preferred prices for drugs. But as the Third Circuit recently recognized in rejecting a materially identical challenge to the Negotiation Program brought by a manufacturer, there is simply “no protected property interest in selling goods to Medicare beneficiaries . . . at a price higher than what the government is willing to pay when it reimburses those costs.” *AstraZeneca*, 137 F.4th at 125-26. None of Plaintiffs’ novel theories escape this principle.

1. Plaintiffs do not contest that “the federal patent laws do not create any affirmative right to . . . sell anything.” Defs.’ Br. at 33 (quoting *Biotechnology Indus. Org., v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007)). And given that “federal patent laws do not confer a right to sell at all, they do not confer a right to sell at a particular price”—including during “a product’s exclusivity period.” *AstraZeneca*, 137 F.4th at 125. Plaintiffs summarily assert that the IRA nevertheless “diminish[es]” manufacturers’ “right to exclude.” Pls.’ Opp’n & Reply at 26-27. But the IRA does not rescind or otherwise alter a manufacturer’s ability to prevent others from “making, using, or selling” a patented drug during the exclusionary period. *Id.* at 26 (quoting *Biotechnology Indus. Org.*, 496 F.3d at 1373). It merely sets the prices that the government pays for drugs through Medicare.

Plaintiffs attempt to sidestep this principle by arguing that the government is acting as a “regulator” rather than as a market participant, because it pays for drugs on behalf of Medicare beneficiaries rather than “for itself.” *Id.* at 24; *see also id.* at 27. But the complexity of this supply chain does not change the key fact that the IRA “only sets prices for drugs *that CMS pays for* when it reimburses” plan sponsors (under Part D) or providers (under Part B). *AstraZeneca*, 137 F.4th at 125-26. It does not set the price for any payments that occur outside the bounds of the IRA. *See* Defs.’ Br. at 35.¹⁰ And in negotiating the price that *the government* will pay, the government is acting as a market participant. Plaintiffs have no right—let alone a constitutional right—to force the government to offer more than it is willing to pay.

¹⁰ In other words, if a Medicare beneficiary seeks to pay cash for a selected drug (instead of going through Medicare), then manufacturers and pharmacies can charge that beneficiary whatever price they want. A beneficiary may choose to pay cash if, for example, the pharmacy’s cash price is cheaper than the beneficiary cost-sharing established by their Part D plan, or the individual does not want to use their insurance for certain medications for any reason.

Plaintiffs’ inapt citation to a handful of Commerce Clause cases only underscores their failure to establish the deprivation of a protected property interest by casting the government as a regulator. *See* Pls.’ Opp’n & Reply at 27. Those Commerce Clause cases expressly turned on federalism concerns that are obviously not present here, *see Cardinal Towing & Auto Repair, Inc. v. City of Bedford*, 180 F.3d 686, 691-92 (5th Cir. 1999) (dormant Commerce Clause may preempt state action where state acts as a “regulator” rather than “as a ‘market participant’”); *Associated Builders & Contractors, Inc. v. Foley*, 37 F.3d 945, 955 n.15 (3d Cir. 1994); *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 92 (1984), nor otherwise relevant in the Fifth Amendment context, *see infra* at 18. And regardless, the government is properly viewed as a market participant even under those cases for the same reasons already explained—the IRA “focuse[s] on the government’s own interests” in paying less for drugs that “its operations require.” *Cardinal Towing & Auto Repair*, 180 F.3d at 691-92.

Plaintiffs also try to warp language from the Fifth Circuit’s standing-and-venue opinion to fit their theory. *See* Pls.’ Opp’n & Reply at 27-28; *Nat’l Infusion Ctr. Ass’n v. Becerra*, 116 F.4th 488, 509 (5th Cir. 2024). But the Fifth Circuit never held that the government is not acting as a market participant; it merely concluded that NICA had sufficiently pled an injury to establish standing, because it “has a concrete interest in not seeing its members’ revenue decrease as a result of allegedly unconstitutional government action.” 116 F.4th at 503. Whether a party has sufficiently pled an economic injury to support standing is a separate question from whether government conduct has deprived the plaintiff of a constitutionally protected property interest. *Compare, e.g., Booker-El v. Superintendent*, 668 F.3d 896, 899 (7th Cir. 2012) (plaintiff adequately pleaded standing based on “a substantial risk in losing benefits”), *with id.* at 900-01 (no property interest in those same benefits).

2. Plaintiffs’ second theory—that the IRA deprives manufacturers of their “right to offer their products at prices set by voluntary agreements”—fares no better. Pls.’ Opp’n & Reply at 23. Again, the IRA “only sets prices for drugs *that CMS pays for* when it reimburses sponsors.” *AstraZeneca*, 137 F.4th at 125-26. It does not govern manufacturers’ “voluntary agreements” outside the bounds of the government’s payment for drugs through Medicare. *See supra* at 15; Defs.’ Br. at 34.

Nor do manufacturers have a freestanding constitutional right “to fix the price at which [they]

will sell' their products." Pls.' Opp'n & Reply at 23 (quoting *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936)). Citing a line of cases that have since been overruled, *Old Dearborn* asserted that legislatures generally may not impair "the right of the owner of property to fix the price at which he will sell" his property in the broader marketplace. 299 U.S. at 192. But the Supreme Court has since held that the Constitution does *not* substantively constrain a legislature's ability to fix the price of goods. See *Olsen v. Nebraska*, 313 U.S. 236, 247 (1941); *Nebbia v. New York*, 291 U.S. 502, 516 (1934). And *Old Dearborn* itself expressly affirmed the validity of legislation that allowed parties to fix the price of goods by contract. 299 U.S. at 192. Thus, even on its terms, *Old Dearborn* did not recognize a freestanding property right to force a price on an unwilling buyer.

Moreover, the IRA does not deprive manufacturers of the ability to "offer their products at prices set by voluntary agreements" because it does not apply to drug sales outside of Medicare, and because participation in Medicare and Medicaid is "completely voluntary." *Chamber*, 696 F. Supp. 3d at 456; Defs.' Br. at 34-36. Plaintiffs cobble together a variety of misplaced and often outdated takings cases to support their "coerci[on]" theory. Pls.' Opp'n & Reply at 24. The three *Lochner*-era cases on which Plaintiffs rely, see *Union Pacific R.R. Co. v. Public Serv. Comm'n of Mo.*, 248 U.S. 67 (1918); *United States v. Butler*, 297 U.S. 1, 54 (1936); *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936), are of limited continuing vitality, see, e.g., *Boehringer Ingelheim*, 2024 WL 3292657, at *15 n.14 (rejecting reliance on these cases in similar challenge to IRA). Regardless, the plaintiffs in those cases were subject to regulatory regimes they could not readily exit, and had to comply with the government's conditions if they wished to sell their products to *anyone*. See *Horne v. Dep't of Agric.*, 576 U.S. 350, 365-66 (2015) (raisin growers could not avoid government property demand if they wished to continue selling any raisins to anyone); *Bowles v. Willingham*, 321 U.S. 503, 520-22 (1944) (Congress sought to regulate the price at which any person could sell or lease his property to *any* buyer); *Union Pacific*, 248 U.S. at 67 (plaintiff was subject to statutory prohibitions against issue of a bond unless the prohibition was waived by a state commission); *Butler*, 297 U.S. 1 (plaintiffs were subject to a tax if they refused to comply with a government regulation, and they could not avoid the tax by declining to participate); *Carter*, 298 U.S. 238 (same). The same analysis does not apply where a party can avoid regulation

simply by forgoing sales through a government program, rather than exiting the industry altogether. *See, e.g., Bristol Myers Squibb*, 2024 WL 1855054, at *6 (rejecting Takings Clause challenge to Negotiation Program and noting that plaintiffs “strategically overlook[] the obvious point that,” in *Horne*, “the only way for raisin growers to avoid the reserve requirement was to stop selling raisins altogether”).¹¹

Plaintiffs cannot rely on the excise tax to show that the IRA is improperly coercive. *See* Pls.’ Opp’n & Reply at 24. The excise tax is one of several options that manufacturers have if they do not wish to participate in the Negotiation Program. *See id.* at 15 (quoting Defs.’ Br. at 35). Participation in Medicare is voluntary. *See, e.g., Bristol Myers Squibb*, 2024 WL 1855054, at *6. A manufacturer could also divest its interest in a selected drug, or cease Medicare sales of that drug while continuing to sell its other drugs to Medicare, or withdraw from Medicare and Medicaid. *See id.* Plaintiffs protest that these alternatives are inadequate because “Medicaid and Medicare are a market unto themselves.” Pls.’ Opp’n & Reply at 25; *see also id.* at 26 n.14. But Plaintiffs have no response to Defendants’ explanation that the size of the Medicare or Medicaid markets do not create “legal compulsion for purposes of the Fifth Amendment,” Defs.’ Br. at 35-36 (quoting *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993)), except to fall back on *Horne*, which is inapposite for the reasons above, *see supra* at 17-18.

Finally, Plaintiffs do not explain how the federalism concerns animating *NFIB v. Sebelius*, 567 U.S. 519 (2012), are relevant here, given that “federalism is immaterial under the Fifth Amendment,” *Douglass v. Nippon Yusen Kabushiki Kaisha*, 46 F.4th 226, 236 (5th Cir. 2022); *see also Fuld v. PLO*, No. 24-151, 2025 WL 1716140, at *8 (U.S. June 20, 2025). In any event, the Supreme Court has reiterated since *NFIB* that “healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions.” *Biden v. Missouri*, 595 U.S. 87, 94 (2022) (per curiam). And the Court has likewise rejected the contention that such “condition[s] [are] impermissibly coercive because the consequence of opting out would be the loss of all Medicare and Medicaid funds.” Response to Application for a Stay Pending Appeal at 27, *Becerra v. Louisiana*, Nos. 21A240, 21A241,

¹¹ This same distinction defeats Plaintiffs’ suggestion that *Horne* “rejected” *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993). Pls.’ Opp’n & Reply at 26. *Garelick* is one of many cases that holds that a party lacks a property interest in participation in Medicare; *Horne* casts no doubt on that analysis.

2021 WL 8939385, at *27 (U.S. Dec. 30, 2021) (citing *NFIB*, 567 U.S. at 580-81 (lead opinion)).¹²

B. Plaintiff NICA’s due process claim lacks merit.

1. Plaintiffs now concede that “providers have no protected interest in being reimbursed at their preferred levels,” Pls.’ Opp’n & Reply at 29, yet still try to maintain a right “to be reimbursed on a non-arbitrary basis at a lawful rate,” *id.* The problem with this is straightforward: Plaintiffs provide no authority to support their conclusory (and circular) assertions that they have a right to be reimbursed at any particular rate, or that the rate of reimbursement under the IRA is otherwise “arbitrary” or not “lawful.” *Id.* Plaintiffs summarily assert that they have a property interest in “the pre-IRA ‘legally prescribed rate’” but provide no statutory entitlement to such rate. *Id.* at 29-30. Indeed, Plaintiffs do not cite to *any* settled interest—in contrast to the plaintiffs in *Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 774 (7th Cir. 2021) (right to the “legally prescribed rate [of reimbursement]”), and *Furlong v. Shalala*, 156 F.3d 384 at 393 (2d Cir. 1998) (right to a preset fee schedule, as interpreted by a consistent pattern of administrative decisions). Plaintiffs cannot simply demand entitlement to their preferred “pre-IRA” reimbursement rates in perpetuity, as a matter of constitutional law.

Searching for some statutory hook, Plaintiffs alternatively note that “the IRA alters the statutory reimbursement formula under both Parts B and D.” Pls.’ Opp’n & Reply at 30. Of course, to the extent that *Congress* has amended a statutory formula, that statutory formula no longer controls and thus no longer grants a statutory right. *See Davis v. Passman*, 442 U.S. 228, 241 (1979) (“Statutory rights and obligations are established by Congress”); *Omar v. McHugh*, 646 F.3d 13, 22-23 (D.C. Cir. 2011) (Congress may “undo . . . statutory rights that it has created”).¹³ And Plaintiffs do not allege

¹² Plaintiffs (at 24) cite *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020), for the proposition that “the ‘total withdrawal of federal funding’ is ‘economic dragooning.’” That quote comes from *NFIB*, which is inapposite here for the reasons explained above. Regardless, Plaintiffs overstate the Third Circuit’s passing reference to the withdrawal of federal funds “in another context.” *Id.*

¹³ Defendants’ opening brief mistakenly indicated that the IRA did not alter “the statutory reimbursement formula for Part B drugs” of “106 percent” of “the volume-weighted average of the average sales price.” Defs.’ Br. at 38 (citations omitted). Although single source drugs generally are subject to that payment limit, *see* 42 U.S.C. § 1395w-3a(b)(1)(B), (b)(4)(A), the IRA altered the payment

that anything about CMS's implementation of the IRA contravenes an existing statutory right.

2. Contrary to Plaintiffs' bare suggestion, it is far from "obvious" how the government's ability to set the terms of its offer to pay *manufacturers* for certain drugs deprives *providers* of their facilities and administrative processes. Pls.' Opp'n & Reply at 30. Nor does the Fifth Circuit's decision bridge the gap. Again, the mere fact that the Fifth Circuit held that the IRA "impacts NICA members' revenue" sufficient to plead standing, *NICA*, 116 F.4th at 503, does not establish that NICA's members have suffered a deprivation of a constitutionally protected property interest, *see supra* at 16. Plaintiffs' theory again boils down to a right to compel the government to pay manufacturers their preferred, higher prices such that providers, in turn, can seek higher reimbursement rates. There is no such constitutional right. *See AstraZeneca*, 137 F.4th at 125.

C. Plaintiff GCCA's due process claim lacks merit.

Plaintiffs now concede that patients "do not have a right to have *all* Medicare and Medicaid products remain available *forever*," but attempt to narrow their asserted right "to *some* life-saving medicines *now*." Pls.' Opp'n & Reply at 29. That is a distinction without a difference. Individual patients have no protected property interest in the future availability of particular prescription medications. *See, e.g., Ledford v. Sullivan*, 105 F.3d 354, 358 (7th Cir. 1997); *Gorney v. Veterans Admin.*, No. 18-cv-531, 2020 WL 5535757, at *6 (D. Ariz. Sept. 15, 2020).

CONCLUSION

The Court should deny Plaintiffs' motion for summary judgment, dismiss Plaintiffs' excise-tax claim for lack of subject-matter jurisdiction, and enter summary judgment for Defendants on all remaining claims.

limit for single source drugs that are selected drugs to "106 percent of the maximum fair price," *id.* § 1395w-3a(b)(1)(B). This does not change the key fact that Plaintiffs fail to cite any currently operative statutory right or other settled interest in their preferred reimbursement rates.

Date: July 3, 2025

Respectfully submitted,

ERIC J. HAMILTON
Deputy Assistant Attorney General
Civil Division

JUSTIN R. SIMMONS
United States Attorney

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Stephen M. Pezzi
STEPHEN M. PEZZI
Senior Trial Counsel
CASSANDRA M. SNYDER
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
(202) 305-8576
stephen.pezzi@usdoj.gov

Counsel for Defendants